INTERNATIONAL STANDARD

ISO/IEEE 11073-30400

First edition
2012-11-01

Health informatics — Point-of-care medical device communication —

Part 30400: Interface profile — Cabled Ethernet

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins —

Partie 30400: Profil d'interface — Ethernet câblé

Reference number
ISO/IEEE 11073-30400:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Institute of Electrical and Electronics Engineers, Inc.
3 Park Avenue, New York • NY 10016-5997, USA
E-mail stds.ipr@ieee.org
Web www.ieee.org

Published in Switzerland

Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE-SA) Standards Board. The IEEE develops its standards through a consensus development process, approved by the American National Standards Institute, which brings together volunteers representing varied viewpoints and interests to achieve the final product. Volunteers are not necessarily members of the Institute and serve without compensation. While the IEEE administers the process and establishes rules to promote fairness in the consensus development process, the IEEE does not independently evaluate, test, or verify the accuracy of any of the information contained in its standards.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is called to the possibility that implementation of this standard may require the use of subject matter covered by patent rights. By publication of this standard, no position is taken with respect to the existence or validity of any patent rights in connection therewith. ISO/IEEE is not responsible for identifying essential patents or patent claims for which a license may be required, for conducting inquiries into the legal validity or scope of patents or patent claims or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance or a Patent Statement and Licensing Declaration Form, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of this standard are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information may be obtained from ISO or the IEEE Standards Association.

ISO/IEEE 11073-30400 was prepared by the IEEE 11073 Standards Comittee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-30400-2010). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. IEEE is responsible for the maintenance of this document with participation and input from ISO member bodies.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication* (text in parentheses gives a variant of subtitle):

— *Part 10101: (Point-of-care medical device communication) Nomenclature*

— *Part 10201: (Point-of-care medical device communication) Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

— *Part 10407: Device specialization — Blood pressure monitor*

— *Part 10408: Device specialization — Thermometer*

— *Part 10415: Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10420: Device specialization — Body composition analyzer*

— *Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)*

— *Part 10471: Device specialization — Independant living activity hub*

— *Part 10472: Device specialization — Medication monitor*

— *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*

— *Part 20601: Application profile — Optimized exchange protocol*

— *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*

— *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*

— *Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet*

— *Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test*

— *Part 91064: (Standard communication protocol) Computer-assisted electrocardiography*

— *Part 92001: (Medical waveform format) — Encoding rules*

Introduction

This introduction is not part of IEEE Std 11073-30400-2010, Health informatics—Point-of-Care medical device communication—Part 30400: Interface profile—Cabled Ethernet.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. They provide automatic and detailed electronic data capture of patient vital signs information and device operational data. The primary goals are as follows:

— To provide real-time plug-and-play interoperability for patient-connected medical devices

— To facilitate the efficient exchange of vital signs and medical device data, acquired at the PoC, in all health care environments

"Real time" means that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second. "Plug and play" means that all the clinician has to do is make the connection between devices. The devices automatically detect, configure, and initiate communication without any other human interaction.

"Efficient exchange of medical device data" means that information that is captured at the Point of Care (e.g., patient vital signs data) can be archived, retrieved, and processed by many different types of applications without extensive software and equipment support, and without needless loss of information. The standards are especially targeted at acute and continuing care devices, such as patient monitors, ventilators, infusion pumps, electrocardiogram (ECG) devices, and so on. They comprise a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced.

This standard defines a communications interface profile. This profile is for a cable-connected, Ethernet-based local area network (LAN) for the interconnection of medical devices.

Specifically, this standard calls out layers 1 and 2 of the Open Systems Interconnection (OSI) reference model (physical and data link layers) communications services and protocols, as implemented in IEEE Std 802.3-2008,[a] that are appropriate for the medical communications environment. This standard is one part of the family of ISO/IEEE 11073 series of standards. It is compatible with the upper layer ISO/IEEE 11073 standards. It is expected that this standard will be combined, as appropriate, with other standards from the ISO/IEEE 11073 series.

The primary users of this standard are technical personnel who are creating or interfacing with a medical communications system. Familiarity with the ISO/IEEE 11073 family of standards is recommended. Familiarity with communications and networking technologies is also recommended.

[a] Information on references can be found in Clause 2.

Health informatics — Point-of-care medical device communication —

Part 30400:
Interface profile — Cabled Ethernet

1 Overview

1.1 Scope

This document focuses on the application of the Ethernet family (IEEE Std 802.3™-2008[1]) of protocols for use in medical device communication. The scope is limited to referencing the appropriate Ethernet family specifications and to calling out any specific special needs or requirements of the ISO/IEEE 11073 environment, with a particular focus on easing interoperability and controlling costs.

1.2 Purpose

This standard defines a comprehensive set of protocols consistent with the ISO/IEEE 11073 and Ethernet family of protocols for common use by medical devices in networked operating contexts. By providing this standard, the ISO/IEEE 11073 design goal to provide real-time plug-and-play interoperability will be extended to a broad set of network interfaces.

[1] Information on references can be found in Clause 2.

2 Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

ANSI/TIA/EIA 568-A-1995, Commercial Building Telecommunications Cabling Standard.[2]

IEEE Std 802.3™-2008, Standard for Information technology—Telecommunications and Information Exchange Between Systems—Local and Metropolitan Area Networks—Specific Requirements Part 3: Carrier Sense Multiple Access with Collision Detection (CSMA/CD) Access Method and Physical Layer Specifications.[3,4]

ISO/IEEE 11073-30200:2004, Health Informatics—Point-of-Care Medical Device Communication—Part 30200: Transport Profile—Cable Connected.[5]

3 Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. *The IEEE Standards Dictionary: Glossary of Terms & Definitions* should be referenced for terms not defined in this clause.[6]

Note that numerous definitions from IEEE Std 802.3-2008 are used in this document. Those definitions will not be repeated here. For specific information, please refer to 1.4 of IEEE Std 802.3-2008.

3.1.1 10BASE-T: A type of Ethernet interface distinguished by its IEEE 802.3 physical layer specification for operation over two pairs of unshielded twisted-pair (UTP) cabling at a media access control (MAC) data rate of 10 Mb/s.

3.1.2 100BASE-TX: A type of Ethernet interface distinguished by its IEEE 802.3 physical layer specification for operation over two pairs of unshielded twisted-pair (UTP) cabling at a media access control (MAC) data rate of 100 Mb/s.

3.1.3 1000BASE-T: A type of Ethernet interface distinguished by its IEEE 802.3 physical layer specification for operation over four pairs of unshielded twisted-pair (UTP) cabling at a media access control (MAC) data rate of 1000 Mb/s.

[2] ANSI publications are available from the Sales Department, American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (http://www.ansi.org/). TIA publications are available from the Telecommunications Industry Association, 2500 Wilson Boulevard, Suite 300, Arlington, VA 22201, USA (http://www.tiaonline.org). EIA publications are available from Global Engineering Documents, 15 Inverness Way East, Englewood, Colorado 80112, USA (http://global.ihs.com/).
[3] IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854, USA (http://standards.ieee.org/).
[4] The IEEE standards or products referred to in this clause are trademarks owned by the Institute of Electrical and Electronics Engineers, Incorporated.
[5] ISO publications are available from the ISO Central Secretariat, Case Postale 56, 1 rue de Varembé, CH-1211, Genève 20, Switzerland/ Suisse (http://www.iso.ch/). ISO publications are also available in the United States from the Sales Department, American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (http://www.ansi.org/).
[6] *The IEEE Standards Dictionary: Glossary of Terms & Definitions* is available at http://shop.ieee.org/.

3.1.4 10GBASE-X: A type of Ethernet interface distinguished by its IEEE 802.3 physical layer specification for operation over four pairs of unshielded twisted-pair (UTP) cabling at a media access control (MAC) data rate of 10 Gb/s.

3.1.5 bedside communications controller (BCC): A communications controller, which is typically located at a patient bedside, that serves to interface between one or more medical devices. The BCC may be embedded into local display, monitoring, or control equipment. Alternatively, it may be part of a communications router to a remote hospital host computer system.

3.1.6 category 5 (Cat 5) balanced cable: The designation applied to 100 Ω unshielded twisted-pair (UTP) cables and associated connecting hardware whose transmission characteristics are specified up to 100 MHz. (ANSI/TIA/EIA 568-A-1995). *See also*: **Class D cable**.

3.1.7 category 5e (Cat 5e) balanced cable: The designation applied to 100 Ω unshielded twisted-pair (UTP) cables and associated connecting hardware whose transmission characteristics are specified up to 100 MHz. This designation is an enhanced version of the Category 5 cable, which adds specifications for far end crosstalk. The Category 5e specification (ANSI/TIA/EIA 568-B.1-2001 [B1]) has deprecated the Category 5 specification. *See also*: **Class D cable**.

3.1.8 Class D cable: A category of cabling specified in ISO/IEC 11801-2002 [B9]. 100BASE-TX uses Class D as specified in the 1995 revision (corresponding to the ANSI/TIA/EIA 568-A specification for Category 5 cabling). 1000BASE-T uses Class D as specified in the 2001 revision (corresponding to the ANSI/TIA/EIA 568-A specification for Category 5e cabling).

3.1.9 collision domain: A single, half duplex mode Carrier Sense Multiple Access (CSMA)/Collision Detection (CD) network. If two or more media access control (MAC) sublayers are within the same collision domain and both transmit at the same time, a collision will occur. MAC sublayers separated by a repeater are in the same collision domain. MAC sublayers separated by a bridge are within different collision domains. (See IEEE Std 802.3-2008.)

3.1.10 device communications controller (DCC): A communications interface associated with a medical device. A DCC may support one or more physically distinct devices acting as a single network communications unit. Its purpose is to provide a point-to-point serial communication link to a bedside communications controller (BCC).

3.1.11 downstream device: A term used to differentiate the two ends of an Ethernet connection. The matching term (identifying the other end of the Ethernet connection) is “upstream device.”

3.1.12 local area network (LAN): A communications network to interconnect a variety of intelligent devices (e.g., personal computers, workstations, printers, and file storage devices) that can transmit data over a limited area, typically within a facility.

3.1.13 management information base (MIB): A type of database used to manage the devices in a communications network. It comprises a collection of objects in a (virtual) database used to manage entities in a network.

3.1.14 management information base (MIB) aggregator: A generic term for a device that combines multiple downstream MIB ports and multiplexes them on to one upstream MIB port.

3.1.15 management information base (MIB) interface: An informal name for the ISO/IEEE 11073-30200:2004.

3.1.16 media access control (MAC): The data link sublayer that is responsible for transferring data to and from the physical layer.

3.1.17 medical device communications (MDCs): A general term used to describe the networking and connectivity standards that enable medical devices to communicate in interoperable ways.

3.1.18 medical information bus (MIB): An informal name for the ISO/IEEE 11073 family of standards. Now deprecated.

3.1.19 octet: A group of eight adjacent bits.

3.1.20 Point of Care (PoC): The area in which clinicians and patients are in close physical proximity and in which specific care, treatments, medical procedures, and/or monitoring are provided to the patient.

3.1.21 registered jack (RJ)-45: **(A)** AT&T Registered Jack designation for the eight-pin modular connectors that meet the requirements of IEC 60603-7:1996 [B5][7] and ISO/IEC 8877:1992 [B8]. **(B)** An eight-pin modular telephone plug.

NOTE 1—Also called a programmable connection, an RJ-45 plug is generally used on four-wire circuits, but it can be used on eight-wire circuits.[8]

NOTE 2—Definition (B) reflects colloquial usage. Standards referencing this term should point to the precise standardized connector specification.

3.1.22 upstream device: A term used to differentiate the two ends of an Ethernet connection. The matching term (identifying the other end of the Ethernet connection) is "downstream device."

3.2 Acronyms and abbreviations

Note that numerous acronyms and abbreviations from the IEEE Std 802.3-2008 are used in this document. Those acronyms and abbreviations will not be repeated here. For specific information, please refer to 1.5 of IEEE Std 802.3-2008.

BCC	bedside communications controller
Cat 5	Category 5
Cat 5e	Category 5, enhanced
DCC	device communications controller
DTE	data terminal equipment
LAN	local area network
MAC	media access control
MDCs	medical device communications
MIB	management information block
PoC	Point of Care
PD	powered device
PSE	power sourcing equipment
RJ	registered jack
STP	shielded twisted pair
UTP	unshielded twisted pair

[7] The numbers in brackets correspond to those of the bibliography in Annex A.
[8] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.

4 Clinical connectivity context

4.1 Clinical Point-of-Care deployment diagram

Figure 1 identifies for the purposes of this standard the cable-connected interface types specified by ISO/IEEE 11073-30200:2004 and this standard, the devices upon which those interface types are deployed, the interconnections between those devices, and the location within the PoC environment where these interfaces are deployed.

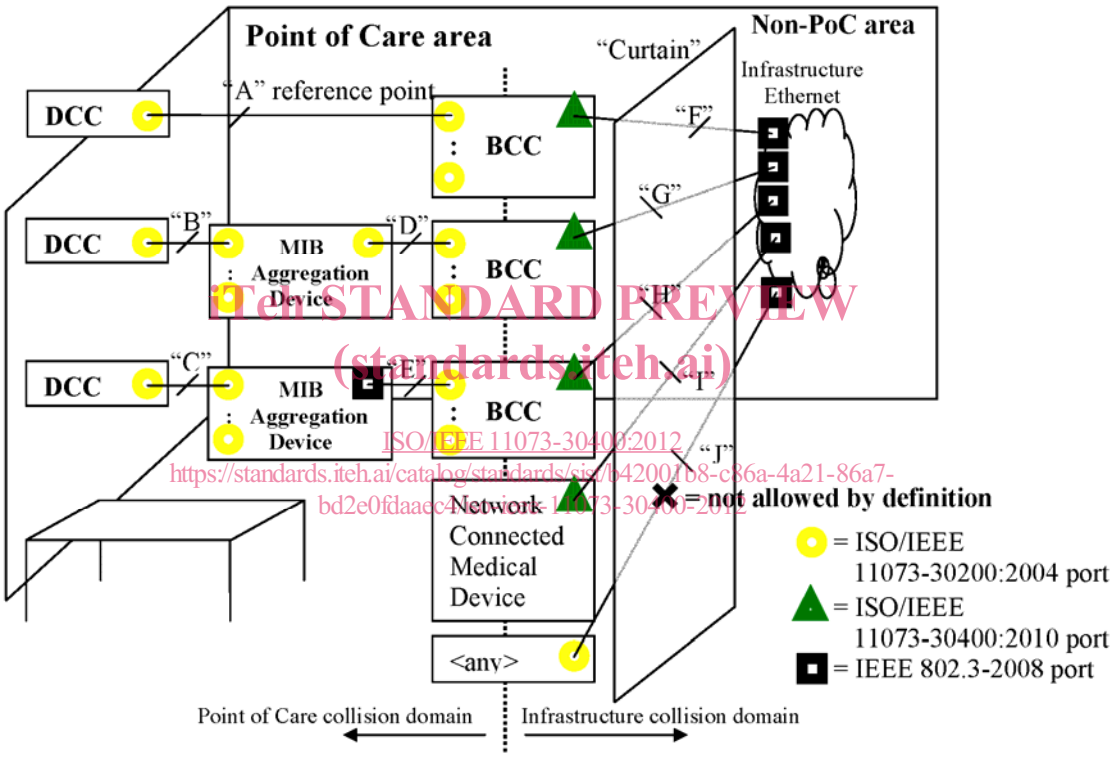

Figure 1—Clinical PoC environment

The interface reference points ("A" through "J") allow the different interface requirements in an overall clinical PoC environment to be appropriately considered and easily referenced. The reference points are described as follows:

- Reference points "A" through "D" between ISO/IEEE 11073-30200 ports.
- Not part of this standard. However, this is shown for completeness with respect to the ISO/IEEE 11073 interfaces deployed in the clinical PoC environment.
- Reference point "E" between ISO/IEEE 11073-30200 ports and IEEE 802.3 ports.
- Not part of this standard. However, this is shown for completeness with respect to the ISO/IEEE 11073 interfaces deployed in the clinical PoC environment. Compatibility is discussed in ISO/IEEE 11073-30200:2004.
- Reference points "F" through "I" between IEEE 11073-30400 ports and IEEE 802.3 ports.

— These are the connectivity options in scope for this document.

— The BCC and the network connected medical device **shall** implement IEEE 802.3 Data Terminal Equipment (DTE) functionality.

— Reference point "J" between IEEE 802.3 ports and ISO/IEEE 11073-30200 ports.

— By definition, ISO/IEEE 11073-30200:2004 is for deployment in a clinical PoC environment. The "J" reference point is between a device in the PoC area and the networking infrastructure. Thus, reference point "J" is a specific example of nonadherence to the definition of PoC area.

4.2 Use of normative references

This standard makes normative reference to IEEE Std 802.3. The specific version of IEEE Std 802.3 that applies in this standard is specified in Clause 2. Although versions of IEEE Std 802.3 are intended to maintain backward compatibility, the user is recommended to undertake an evaluation of any version of IEEE Std 802.3 not specified in this standard before use of that version.

A device that adheres to this standard and thus to the relevant clauses of IEEE Std 802.3 shall not imply that the device conforms to electrical or performance characteristics of other standards or that it complies with regulatory issues.

4.3 High-level intent

This standard specifies the subset of the IEEE 802.3 specification that shall be allowed for use in a medical device communication environment. Specifically, it specifies the use of the IEEE 802.3 physical signaling interfaces utilizing unshielded twisted pair cabling.

— 10BASE-T (2 pairs required) **shall** use Class D-1995 (Category 5) or better unshielded twisted pair (UTP) cabling

— 100BASE-TX (2 pairs required) **shall** use Class D-1995 (Category 5) or better UTP cabling

— 1000BASE-T (4 pairs required) **shall** use Class D-2001 (Category 5e) or better UTP cabling

Shielded twisted pair (STP) cable **shall not** be used.

Further IEEE 802.3 functionality that is specified includes the following:

— Auto negotiation.

— Medium dependent interface crossover or MDI-X (the "X" representing "crossover"). It is also called Auto-MDI, Universal Cable Recognition, or Auto Sensing. This eliminates the need for crossover cables, obsoletes the uplink/normal ports and manual selector switches found on many older Ethernet hubs and switches, and vastly reduces installation errors, especially by nontechnical users.

— Power over Ethernet.

Beyond the supported Ethernet signaling and powering capabilities, there are also labeling, color coding, and related issues that are specific to the medical device communication environment.

NOTE 1—Although it is the intention of the IEEE 11073-30400 specification to support a UTP-based interface, it is not the intention to preclude any fiber deployment "elsewhere" in the networking infrastructure, nor is it the intention to include any language in the IEEE 11073-30400 specification that would limit any future ISO/IEEE 11073-3xxyy specification from covering a direct fiber optic interface.

NOTE 2—Although it is the intention of the IEEE 11073-30400 specification to support 10, 100, and 1000BASE interfaces, it is not the intent to preclude any other IEEE 802.3 interfaces deployed "elsewhere" in the networking infrastructure, nor is it the intention to include any language in the IEEE 11073-30400 specification that would limit any future ISO/IEEE Std 11073-3xxyy specification from covering other IEEE 802.3 interfaces.

NOTE 3—Although it is the intention of the IEEE 11073-30400 specification to support a UTP-based interface, it is not the intent to preclude any backplane deployment "elsewhere" in the networking infrastructure, nor is it the intention to include any language in the IEEE 11073-30400 specification that would limit any future ISO/IEEE 11073-3xxyy specification from covering a backplane interface.

4.4 Mapping "PoC reference points" to "high-level intent"

To accommodate legacy and contemporary medical device communication devices within the IEEE 802.3 network infrastructure, this standard defines three groups with different IEEE 802.3 features. These are referred to as *Legacy*, *Standard*, and *Performance* feature groups.

The three feature groups are summarized and mapped to the clinical PoC environment in Table 1. The normative definition mapping all of the IEEE 802.3 features to each of the feature groups is contained in Clause 6.

Devices conformant with this standard shall implement either feature group *Legacy*, *Standard*, or *Performance* (see Table 1).

Table 1—Mapping "PoC reference points" to "high-level intent"

Reference point: "interface end"	Applicability	Feature group name	IEEE 11073-30400 Ethernet feature group characteristics			
			Port type	Duplex	MDI-X	Power over Ethernet
F through I: "downstream" port	This feature group **may** be used.	*Legacy*	10BASE-T 100BASE-TX Fixed	Fixed half	No	Yes
F through I: "downstream" port	This feature group **shall not** be used.		10BASE-T 100BASE-TX Fixed	Fixed full[a]	x	x
F through I: "downstream" port	One of these two feature groups **should** be used.	*Standard*	10BASE-T 100BASE-TX auto negotiation	Half/full auto negotiation	Yes	Yes
		Performance	10BASE-T 100BASE-TX 1000BASE-T auto negotiation	Half/full auto negotiation	Yes	Yes
F through I: "upstream" port	One of these two feature groups **shall** be used.	*Standard*	10BASE-T 100BASE-TX auto negotiation	Half/full auto negotiation	Yes	Yes
		Performance	10BASE-T 100BASE-TX 1000BASE-T auto negotiation	Half/full auto negotiation	Yes	Yes

[a]In Ethernet, a duplex mismatch is a condition where two connected devices operate in different duplex modes. More specifically, one device operates in half duplex, whereas the other one operates in full duplex. Duplex mismatch may result from manually setting two connected network interfaces at different duplex modes. It will also result if one connected device performs autonegotiation while the other device is manually set to a full duplex mode. The implications of a duplex mismatch are an Ethernet interface that has extremely low to no effective throughput.